Purpose: Development of a comprehensive policy for storage, access, and release of newborn screening dried blood spot specimen/information forms.

## Background

The newborn screening dried blood specimen is somewhat unique among specimens typically dealt with by the Department of Health's Public Health Laboratories:

- The dried blood spots are relatively stable and capable of being stored for long periods with no special processing.
- The dried blood spots and specimen information are contained on a single form and are not easily separated.
- The pattern of "punches" taken from the dried blood spots provides indirect information about the testing performed on them.
- DNA contained in the dried blood can provide information to positively link the specimen to a specific child (in the event of uncertainty regarding accuracy of identifying information).

## Definitions:

The Public Health Laboratories is a "Health care facility" as defined by the Uniform Healthcare Information Act, RCW 70.02.010(5): "…a hospital, clinic, nursing home, laboratory, office or similar place where a health car provider provides health care to patients".

The Office of Newborn Screening is a "Health care provider" as defined by the Uniform Healthcare Information Act, RCW 70.02.010(7): "…a person who is …authorized by the law of this state to provide health care in the ordinary course of business…"

The Office of Newborn Screening is also a "Person" as defined by the Uniform Healthcare Information Act, RCW 70.02.010(11): "…an individual, corporation…government, governmental subdivision or agency, or any other legal or commercial entity."

Newborn Screening is "Health care" as defined by the Uniform Healthcare Information Act, RCW 70.02.010(4): "…any care, service, or procedure provided by a health care provider: (a) to diagnose, treat, or maintain a patient's physical or mental condition;"

The newborn screening specimen/information form (including dried blood specimen) is "Health care information" as defined by the Uniform Healthcare Information Act, RCW 70.02.010(6): "…any information, whether oral or recorded in any form or medium, that identifies or can readily be associated with the identity of a patient and directly relates to the patient's health care, including a patient's deoxyribonucleic acid..."

## Policies

1. **Ownership: The specimen and information form is the property of the State of Washington**.

   *Rationale: RCW 40.14.020 states: "All public records shall be and remain the property of the state of Washington." The information portion of the form is clearly a "public record" as defined in Section 010 of that statute. It is less clear, however, whether the definition includes the dried blood specimen portion since the central concept is that of a "…document, regardless of physical form or characteristics…" Nonetheless, it seems reasonable to extend the concept of public record to "health care information"(as defined in 70.02.010) that is collected by a public entity such as the Newborn Screening Program. As such, the "public record" includes the dried blood specimen.*

   *Also, the concept of ownership of health care information by the health care facility that possesses it is consistent with the other provisions of Chapter 70.02 RCW.*

   *Finally, Assistant Attorney General Richard McCartan concluded in a memo to Michael Glass dated May 22, 2001 that the dried blood specimen is not a public record covered in the public disclosure law, Chapter 42.17 RCW. In follow-up correspondence on May 25, 2001 he offered "My opinion is that the specimens "belong" to the Department…" (of Health).*

2. **Storage: The specimen/information forms shall be kept at ambient temperature in secured storage to preserve their confidentiality and prevent access by unauthorized persons.**

   *Rationale: RCW 70.02.150: Security Safeguards; requires that "A health care provider shall effect reasonable safeguards for the security of all health care information it maintains".*

   *Many of the chemical components of the specimen are more stable at refrigerated temperatures, however, preservation of chemical integrity is not necessary for the primary purpose of storage. A possible exception could be the use of DNA to validate specimen identification, however, since DNA remains stable under a wide range of storage conditions the additional cost of refrigerated storage is not warranted.*

3. **Retention/destruction: The specimen/information forms shall be retained until the child is 21 years old. Since specimens are collected during the first weeks of life, this will be achieved by retaining the forms for 21 years. After this time the form will be destroyed by incineration.**

*Rationale: Washington's Medical Test Site Rules (WAC 246-338-070) specify minimum retention times for laboratory records of, from 2 years for most specialties, to ten years for cytology reports, histopathology reports and and stained slides. The longer retention for newborn screening records is consistent with requirements for hospitals (RCW 70.41.190) which must "…retain and preserve all medical records which relate directly to the care and treatment…of minors…for a period of no less than three years following the attainment of the age of eighteen years…" (emphasis added) The same requirements are applied to hospice (WAC 246-331-165) and home health care (WAC-327-165).*

*This is also consistent with published recommendations regarding legal liability for newborn screening programs: "… lawsuits could generally be brought until the infant is 21 years of age…Records should be maintained until the last possibility that an individual may bring a lawsuit based on that screening." (Andrews, JD, editor. Legal liability and quality assurance in newborn screening, p55, American Bar Foundation, Chicago IL, 1985).*

*Incineration is the only reliable, cost effective method to assure the complete destruction of the dried blood specimen.*

4. **Access: Access to stored specimen/information forms shall be restricted to Department of Health employees and those contractors or others approved by the Director of Newborn Screening as necessary to meet specific program needs. Access is contingent upon compliance with all applicable state laws, regulations, and policies safeguarding the privacy and confidentiality of medical information. The Director shall assure that those granted access understand confidentiality requirements and have a signed confidentiality agreement on file.**

   *Rationale: Consistent with agency and division policy, this provision provides physical security while allowing access necessary to meet legitimate agency and program needs. It further provides that those with access understand and follow confidentiality/privacy restrictions.*

5. **Release: Dried blood spot samples and specimen information will only be released according to the following:**

A sample from a specimen and copies of associated information (demographics and testing results, if requested) will be released to:

- A health care provider at the request of the patient or their legal representative after completing and signing the form "Release of Information: Newborn Screening Specimen".
- A researcher with the written, informed consent of the patient or their legal representative as part of a research project that has been reviewed and approved

by the DOH/DSHS Human Subjects Review Board and the Secretary or designee of the Department of Health.
- A named person in a legally executed subpoena following review and approval of the State Attorney General.

Anonymous samples may be released when the intended use has significant potential health benefit and each of the following criteria have been met:

- The investigation design is adequate to assure anonymity will be preserved.
- All newborn screening tests have been completed and the status of the infant is resolved.
- At least one fully adequate spot will remain after the anonymous sample has been taken.
- Sufficient resources (personnel) are available for extracting the samples.
- The DOH/DSHS Human Subjects Research Review Board has reviewed and approved the investigation. This requirement may be waved by the Director of Newborn Screening for a very small (i.e.: less than 100 sample) pilot study where the intent is to evaluate a testing tool, as opposed to an evaluation where the intent is to measure some characteristic of a population).

Dried blood samples and specimen information will not be released directly to a patient, their parent or legal representative except as described above.

*Rationale: This has been designed to be consistent with State laws, regulations and policies, notably the requirements of the Chapter 70.02 RCW, the Uniform Health Care Information Act and Chapter 42.48 RCW, Release of Records for Research. It is intended to prevent violation of any person's privacy or confidentiality of their private information while allowing appropriate medical, legal, and research uses.*

*The restriction against releasing specimens directly to parents is consistent with our established procedures of working through the patient's health care providers regarding screening outcomes WAC 246-650-020(2): "…the department shall…(b) report significant screening test results to the infant's attending physician…and (c) offer …resources of the department to physicians attending infants…" and in part by RCW 70.02.090(3) which stipulates that a provider who denies a patient's request to examine or copy medical information shall allow examination and copying by another health care provider selected by the patient.*

*Richard McCartan, Assistant Attorney General reviewed these requirements and his May 22, 2001 memo to Michael Glass concluded that they "…appear consistent with the law."*

6. **Notification: The Department of Health shall notify parents of the specimen storage, retention and access policy and their rights under Chapter 70.02**

**RCW through the pamphlet "*Newborn Screening and Your Baby" (DOH publication 304-007)* that is included with the newborn screening specimen/information form.**

*Rationale: Hospitals, clinics and other health care facilities that collect specimens for newborn screening are required to inform patients of their health care information practices (RCW 70.02.120) and typically include language in informed consent documents regarding specimens or biological samples that may be collected in the course of care. However, because the screening is not discretionary, and because the department of health maintains records, including the specimens, on those screened, a separate notification of practices is consistent with the intent of both the Uniform Health Care Information Act and the Governor's Executive Order 00-03. Further justification is provided by our finding that few health care facilities or parents are aware of our practices.*

*The pamphlet "Newborn Screening and Your Baby" (DOH publication 304-007) is specifically designed to provide parents with information about screening as required by WAC 246-650-020. A copy of this pamphlet is included with each specimen collection kit provided to health care providers and thus provides a convenient and effective method for informing parents of these policies.*